

REMARKS

The interview of 5 May 2006 with Examiner Choi is appreciated. The matters discussed included amendments to the claims as set forth herein, and discussion of Matsuoka, Sobrino-Fay and Cleveland *et al.*, all of record, with regard to these claims. Antecedent basis for the added language in independent claims 1 and 13 is found on pages 2 and 7 of the specification.


Briefly, it was noted that Matsuoka *et al.* used a PEG isotonic solution (isosmotic solution, salt solution), that is one containing the same amount of electrolytes as found in the blood [see "Discussion", paragraph (c)]; and that Cleveland *et al.* describe known laxative PEG solutions which commonly do not include electrolytes as the liquid volumes of the dosages are far smaller than those used in bowel cleansing applications and do not present any significant risk of electrolyte loss in use. Further, the Cleveland compositions do not include sodium phosphate (NaP), and there is no motivation for doing so. Sobrino-Faya does not mention electrolytes; however, the widely commercially-available PEG solutions GoLytely®, NuLytely®, and Half-Lytely®) all contain electrolytes but are commonly informally referred to as "PEG" bowel cleansers. Also, Applicant submitted two documents to the Examiner which discuss prior art bowel cleansers; both broadly describe prior art PEG bowel cleansers as containing electrolytes: Gastrointest Endosc, 54: 705-13, November 2001; and a PCT document assigned to Braintree. That said, Applicant notes that the burden is on the Examiner to support §102 and §103 rejections with explicit prior art teachings, not speculations about what the prior art could mean.

Sobrino-Faya describes a PEG /NaP bowel-cleansing solution containing 1500 ml PEG and "a standard dose of NaP" (90 ml), presumably comparable to Fleet Phospho-Soda (US) (59.4g/90 ml, PDR, of record) ) or the Fleet Phospho-Soda of Matsuoka *et al.* (66g/90 ml). These amounts of NaP are much higher than Applicant's NaP range, which was developed with the intent to substantially decrease the amount of NaP ingested to well below

these "standard" levels while maintaining efficacy, in order to avoid the risks and side effects of standard amounts, as discussed at length in the specification. Again, however, the Examiner has not met his burden of proof of obviousness: Applicant's dosage ranges and proportions are essential for obtaining the results described, but the cited references do not specify the actual amounts of either NaP or PEG in the described solutions. It is noted that the Matsuoka and Sobrino-Faya are both foreign publications, and can be used as prior art only to the extent of their written descriptions under 35 USC §102.

In view of the foregoing, it is submitted that the claims are now in condition for allowance, and early favorable action is earnestly solicited.

Respectfully submitted,

  
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